

REMARKS

Applicants request entry of this amendment. Claims 34-56 will remain pending following entry of the amendment. This amendment is supported by the claims and specification as originally filed, and no new matter is introduced by this amendment.

Specification

An amendment to the specification is presented to correct the title of the invention.

Claims Rejections

35 U.S.C. § 112

Claims 34-56 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Independent claims 34 and 37 have been amended to treatment of a wound area of one of a skin flap and skin graft without recitation of "at least one" as including both. Withdrawal of the rejection is respectfully requested.

35 U.S.C. § 103(a)

Claims 34-37, 39-48 and 50-56 stand rejected under 35 U.S.C. § 103(a), as being unpatentable over U.S. Patent No. 6,390,995 to Ogden et al. ("Ogden") in view of "Shock Waves on Microcirculation in Critical Limb Ischemia" by Sanctis ("Sanctis"), in view of U.S. Patent No. 5,904,659 to Duarte ("Duarte"). Applicants respectfully traverse and request reconsideration and withdrawal of these outstanding rejections.

Specifically, none of the cited references individually or in combination provide predictable instruction to one of ordinary skill in the art for the effective use of shock waves to improve healing and survivability of a skin flap or skin graft of a wound area.

At page 4 of the Final Office Action, it is acknowledged that Ogden as modified by Sanctis fails to teach applying acoustic waves to specifically treat skin grafts. It is

similarly submitted that modified Ogden also fails to teach treating skin flaps with shock waves. Ogden's teachings are limited to treatment of bone environments and musculoskeletal tissues. In comparison, the method of the present invention to treat skin flap and grafts is in a skin environment with different tissues, blood supplies and a specialized intended result of attachment of the living tissue flap or graft at the area. Ogden does not suggest that shock wave treatment or associated parameters for internal bone and musculoskeletal tissues are predictable and correlate for the treatment of complex skin flap and grafts involving markedly different tissue environments and attachment objectives.

Like Ogden, Sanctis fails to predictably instruct applicants' discovered treatment methods for attachment and survival of skin tissues. Although it is suggested at page 4 that the Sanctis abstract discloses a shock wave applicator "applied to the skin," this disclosure is not referring to any treatment of the skin but only to the general coupling of shock wave transducer to the body at a person's healthy skin to deliver shock waves into the deeper, targeted non-skin tissues of the body (as also described by Ogden and known for extracorporeal shock wave treatments). Sanctis specifically states in the abstract that a "parabolic reflector is coupled to the skin with silicon water cushion" and that "depth of target within the patient's foot of about 70 mm."

One of ordinary skill in the art would understand both Sanctis and Ogden guiding only treatments of soft tissues deep within the body and chronic conditions associated with such internal environments. Such prior art does not suggest to one of ordinary skill in the art that the delivery of shock waves through healthy skin to arrive at a target of different soft tissues within the body could be used to treat skin flaps or grafts at an external wound area having different blood supply requirements to attach skin tissues. In this regard, Sanctis' and Ogden's acknowledgment of shock waves increasing microcirculation within deeper non-skin soft tissues of the body, does not recognize or suggest any correlation for shock wave treatments being predictably effective to improve attachment of skin flaps and grafts at an acute wound area. Graft and flap treatment targets are different tissue environments and the intended result of viably

attaching such skin tissues versus is distinct from an internal chronic condition of bone and soft tissues.

Without hindsight as to applicant's own recognition of the need for better skin flap and graft healing and further discovery that shock waves can provide improved healing and survivability for flap and graft attachment by inhibiting growth of necrotic zone in skin tissue (claim 47 and dependents thereof), Ogden's and Sanctis' internal tissue treatments do not prospectively guide ordinarily skilled practitioners to treat skin grafts and flaps. Further, any individual Ogden and Sanctis parameters that arguably overlap separate parameters of the claimed invention of claim 34-46 and 50-54 are suggested independently for internal soft tissue treatment purposes without any predictable guidance that the claimed invention's combination of treatment ranges might lead to improvements in the attaching and healing of skin grafts and flaps.

Duarte's disclosure of wound treatment with low frequency ultrasound (including non-longitudinal shear waves therefrom) does not cure the deficiencies of the shock wave treatments of Ogden and Sanctis. Although Duarte and Ogden/Sanctis generally disclose medical treatment with acoustic waves, the strong differences in characteristics and effect between ultrasound waves (Duarte) and shock waves (Ogden/Sanctis) on the bodies of humans and animals are well-known to those of ordinary skill in the art. *See Ogden '995 "Background" at col. 1 and 2.* Applicants respectfully submit the an ordinarily skilled practitioner cannot predictably substitute ultrasound for shock waves that are not similar in form, propagation, intensity or scope of stimulative effect to a target tissue environment, particularly where the cited Ogden reference instructs these differences.

Absent hindsight as to Applicants' invention, there also appears to be no rationale for one of ordinary skill in the art who understands Ogden's and Sanctis' shock wave treatments for internal soft tissue to be guided to look to Duarte's treatment of ulcers and ulcerated wounds with ultrasound to somehow modify Ogden and/or Sanctis for arriving at improved skin flap and graft attachment. Neither Ogden or Sanctis suggest the desirability of using shock waves to treat other than bone and



muscoskeletal tissue with associated chronic conditions deep within the body. And even if Duarte is generally appreciated for use of acoustic waves generally for wound environments, the reference teaches to use ultrasound without any direction for a skilled practitioner to alternatively modify shock wave treatments of Ogden and Sanctis with ultrasound teachings to improve attachment of a skin graft or flap. Given Duarte's different technology for medical treatment and different treatment target environment, Applicants respectfully submit that such reference does not offer predictable guidance for modifying Ogden and Sanctis that enables an ordinarily skilled practitioner to obviously arrive at the claimed invention.

Claims 38 and 49 stand rejected under 35 U.S.C. § 103(a), as being unpatentable over Ogden in view of Sanctis, in view of Duarte, as applied to claims 37 and 46 above and in further view of Applicants' admission of record. Applicants respectfully traverse and request reconsideration and withdrawal of these outstanding rejections to the rejected dependent claims at least in view of the preceding arguments.

In view of the presented amendment and for at least the foregoing reasons, Applicants respectfully request that a timely Notice of Allowance be issued in this case. Applicants' Attorney also cordially invites the Examiner to contact the undersigned at the telephone number provided below if such will advance the prosecution of the instant application.

Applicants have included a petition and the requisite fee for a one-month extension of time under 37 C.F.R. §1.136. Such additional extension fee should also be charged to Deposit Account No. 50-0206, Order No. 69643.000021. Any overpayment can be credited to Deposit Account No. 50-0206, Order No. 69643. 000021. If any additional fees or extensions are due in connection with the filing of this Amendment or the accompanying papers, or otherwise in the course of prosecution of this application, the same are authorized, and please charge the fees to Hunton & Williams Deposit Account No. 50-0206, Order No. 69643.000021.

Respectfully submitted,


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